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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,676	07/16/2001	Zheng Xin Dong	00537-187002	2104

7590 09/15/2005

Biomeasure Incorporated  
27 Maple Street  
Milford, MA 01757

EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/856,676

Applicant(s)

DONG ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06/2005.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

Response to restriction requirement filed 06/08/2005 is acknowledged. Applicant elected, with traverse, Group I, claims 1-9. First, applicant submits that special technical feature addressed in the lack of unity requirement as Group II is misidentified because Group II addresses just one claim directed to a particular effect of peptides of Group I. Examiner fully agrees with this comment and apologizes for an inadvertent typographical error on p.4, line 2 of the previous communication. However, it should have been quite clear that the mention of Group II was an unintentional error because, first, the immediately preceding sentence properly states that "Group I (not Group II) is the technical feature that links Group I to III"; second, the same paragraph discusses that the art teaching the special technical feature should teach GLP-1 derivatives (and not the method of their use). Therefore, it would be clear that the meaning of the lack of unity statement addressed Group I being the common technical feature, and not Group II. Applicant did not address such apparent possibility. Instead, applicant offers traverse of the division of the Groups based on the US practice restriction requirement. Examiner maintains that the claims are subject of lack of unity requirement and that there is no "special" technical feature linking inventions I-III as the compounds of Group I (as read in full breadth of claim 1) do not constitute a "special technical feature" as they are taught or suggested by prior art, the disorder conditions recited in claims 11,12 have no common feature as claimed as they are not related to each other, have different mechanisms of development and etiology. Further, the

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methods of treatment have different enablement requirements. In addition, as was stated in the restriction requirement, if a product claim is found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. The requirement is still deemed proper and is therefore made FINAL. Claims 10-12 are withdrawn from further consideration by the examiner as being drawn to a non-elected groups.

With respect to election of species, applicant elected compound [Hppa<sup>7</sup>]hGLP-1(7-36)-NH<sub>2</sub>. Claims 1-9 are addressed to the extent they read on the elected species.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement filed 06/08/2005 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. The claims, to the extent they read on the elected species, are directed to hGLP-1(7-36)-NH<sub>2</sub> derivative having residue "Hppa" in 7<sup>th</sup> position. The meaning of the term Hppa is not disclosed in the specification. While specification mentions such residue as one of possible des-residues (p. 9, line 8), and explains meaning of other abbreviations (p. 9-10), it does not explain the meaning of abbreviation Hppa. Consequently, the term Hppa renders the claim indefinite<sup>1</sup>.

***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As addressed in the rejection under 35 U.S.C. 112, second paragraph, above, the term "Hppa" is not defined in the specification. Therefore, the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

***Conclusion.***

No claims are allowed.

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<sup>1</sup> And, consequently, the claimed subject matter can not be searched.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb